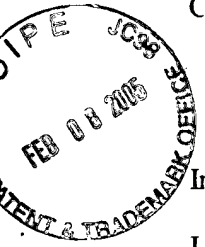


Attorney Docket No.: 330310.00103
Customer No. 27160

U.S. Patent Application No.
10/669,250



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Leland SHAPIRO

Application No.: 10/669,250

Filed: September 25, 2003

For: INHIBITORS OF SERINE PROTEASE
ACTIVITY, METHODS AND
COMPOSITIONS FOR TREATMENT
OF NITRIC OXIDE INDUCED
CLINICAL CONDITIONS

:
:
: Group Art Unit: 1645
:
: Examiner: Not Yet Assigned
:
: Confirmation No.: 3190
:
: Atty. Dkt. No.: 330310.00103

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

February 8, 2005

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

In compliance with the duty of disclosure under 37 C.F.R. §1.56 and in accordance with the practice under 37 C.F.R. §§1.97 and 1.98, the Examiner's attention is directed to the documents listed on the enclosed Forms PTO/SB/08A and PTO/SB/08B. Please note that these documents were all considered in related application 09/518,097, filed March 3, 2000; now U.S. Patent No. 6,489,308, issued December 3, 2002. For the convenience of the Examiner a partial copy of the above patent with the listed references is enclosed. The citation numbers have been marked on the patent for ease of comparison.

FORMAL MATTERS

In accordance with 37 C.F.R. § 1.97(b)(3), since a first Official Action on the merits of the subject application has not yet been issued, neither a certificate, petition nor payment of a fee is believed to be required for this Information Disclosure Statement. However, the Commissioner is hereby

Attorney Docket No.: 330310.00103
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U.S. Patent Application No.
10/669,250

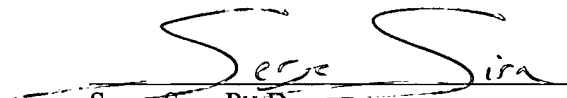
authorized to charge any fee which may be required in connection with this paper to Deposit Account No.
50-1710.

CONCLUSION

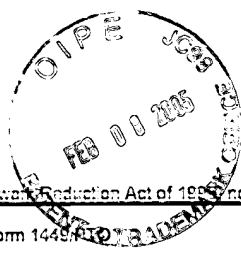
It is respectfully requested that the above information be considered by the Examiner and that a copy of the enclosed Forms PTO/SB/08A and PTO/SB/08B be returned indicating that such information has been considered.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should continue to be directed to our address given below.

Respectfully submitted,


Serge Sira, PH.D.
Attorney for Applicant
Registration No. 39,445

Patent Administrator
KATTEN MUCHIN ZAVIS ROSENMAN
525 West Monroe Street, Suite 1600
Chicago, Illinois 60661-3963
(202) 625-3500



PTO/SB/03A (03-03)

Approved for use through 07/31/2008. OMB 0651-0031

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**INFORMATION DISCLOSURE
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(Use as many sheets as necessary)

Complete if Known

Application Number	10/669,250
Filing Date	September 25, 2003
First Named Inventor	Leland SHAPIRO
Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	330310.00103

Sheet 1 of 17

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1	US- 4,021,472 A	05/1977	Fujii et al.	
	2	US- 4,051,842 A	10/1977	Hazel et al.	
	3	US- 4,140,122 A	02/1979	Kuhl et al.	
	4	US- 4,224,342 A	09/1980	Fujii et al.	
	5	US- 4,283,418 A	08/1981	Fuji et al.	
	6	US- 4,310,533 A	01/1982	Uegai et al.	
	7	US- 4,383,529 A	05/1983	Webster	
	8	US- 4,629,567 A	12/1986	Bollen et al.	
	9	US- 4,657,763 A	04/1987	Finkelstein	
	10	US- 4,668,504 A	05/1987	Kahan et al.	
	11	US- 4,711,848 A	12/1987	Insley et al.	
	12	US- 4,713,224 A	12/1987	Tamhankar et al.	
	13	US- 4,732,973 A	03/1988	Barr et al.	
	14	US- 4,760,130 A	07/1988	Thompson et al.	
	15	US- 4,788,603 A	11/1988	Fujimura et al.	
	16	US- 4,829,052 A	05/1989	Glover et al.	
	17	US- 4,839,283 A	06/1989	Kawasaki et al.	
	18	US- 4,843,094 A	06/1989	Imaki et al.	
	19	US- 4,889,723 A	12/1989	Kim et al.	

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		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	20	WO 94/07525	04/1994			
	21	WO 95/28422	10/1995			
	22	WO 95/34538	12/1995			
	23	WO 96/12021	04/1996			
	24	WO 96/14067	05/1996			
	25	WO 97/03679	02/1997			

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	330310.00103

Sheet 2 of 17

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		Number-Kind Code ² (if known)			
	26	US- 4,931,279 A	06/1990	Bawa et al.	
	27	US- 4,963,654 A	10/1990	Katunuma	
	28	US- 5,004,612 A	04/1991	Kim et al.	
	29	US- 5,077,428 A	12/1991	Imaki et al.	
	30	US- 5,110,602 A	05/1992	Kim et al.	
	31	US- 5,157,019 A	10/1992	Glover et al.	
	32	US- 5,166,134 A	11/1992	Lezdey et al.	
	33	US- 5,175,253 A	12/1992	Fallon et al.	
	34	US- 5,214,191 A	05/1993	Kirschenheuter et al	
	35	US- 5,216,022 A	06/1993	Oleksyszyn et al.	
	36	US- 5,240,956 A	08/1993	Kirschenheuter et al	
	37	US- 5,247,084 A	09/1993	Imaki et al.	
	38	US- 5,399,346 A	03/1995	Anderson et al.	
	39	US- 5,416,191	05/1995	Cheronis et al.	
	40	US- 5,420,110 A	05/1995	Miller et al.	
	41	US- 5,432,178 A	07/1995	Nakai et al.	
	42	US- 5,470,970 A	11/1995	Saeger et al.	
	43	US- 5,476,995 A	12/1995	Clark et al.	
	44	US- 5,478,727 A	12/1995	Roizman et al.	

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		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	45	WO 97/09346	03/1997			
	46	WO 97/09347	03/1997			
	47	WO 97/10222	03/1997			
	48	WO 97/10231	03/1997			
	49	WO 97/21690	06/1997			
	50	WO 97/24339	07/1997			

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First Named Inventor	Leland SHAPIRO
Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	330310.00103

Sheet 3 of 17

U. S. PATENT DOCUMENTS

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		Number-Kind Code ² (if known)			
	51	US- 5,486,470 A	01/1996	Darke et al.	
	52	US- 5,489,593 A	02/1996	Palmer et al.	
	53	US- 5,504,094 A	04/1996	Nakane et al.	
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	57	US- 5,532,215 A	07/1996	Lezdey et al.	
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	60	US- 5,593,858 A	01/1997	Fleer et al.	
	61	US- 5,604,201 A	02/1997	Thomas et al.	
	62	US- 5,610,140 A	03/1997	Goodfellow et al.	
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	64	US- 5,614,555 A	03/1997	Nakai et al.	
	65	US- 5,616,693 A	04/1997	Hwang et al.	
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	69	US- 5,641,670 A	06/1997	Treco et al.	

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		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
	70	WO 97/31937	09/1997			
	71	WO 97/33996	09/1997			
	72	WO 97/37969	10/1997			
	73	WO 97/45402	12/1997			
	74	WO 97/48706	12/1997			
	75	WO 97/49679	12/1997			

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First Named Inventor	Leland SHAPIRO
Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	330310.00103

Sheet 4 of 17

U. S. PATENT DOCUMENTS

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		Number-Kind Code ² (if known)			
	76	US- 5,663,416 A	09/1997	Kirschenheuter et al	
	77	US- 5,665,589 A	09/1997	Harris et al.	
	78	US- 5,700,779 A	12/1997	Goodfellow et al.	
	79	US- 5,710,026 A	01/1998	Sprecher	
	80	US- 5,712,117 A	01/1998	Sprecher	
	81	US- 5,747,645 A	05/1998	Sprecher	
	82	US- 5,750,506 A	05/1998	Goodfellow et al.	
	83	US- 5,759,548 A	06/1998	Bathurst et al.	
	84	US- 5,780,009 A	07/1998	Karatzas et al.	
	85	US- 5,798,442 A	08/1998	Gallant et al.	
	86	US- 5,801,148 A	09/1998	Gyorkos et al.	
	87	US- 5,804,594 A	09/1998	Murad	
	88	US- 5,807,829 A	09/1998	Gyorkos et al.	
	89	US- 5,811,241 A	09/1998	Goodfellow et al.	
	90	US- 5,817,484 A	10/1998	Yu et al.	
	91	US- 5,834,431 A	11/1998	Stewart et al.	
	92	US- 5,843,900 A	12/1998	Cheronis et al.	
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	94	US- 5,861,299 A	01/1999	Archibald et al.	

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	95	WO 98/06417	02/1998			
	96	WO 98/09206	03/1998			
	97	WO 98/20034	05/1998			
	98	WO 98/21186	05/1998			
	99	WO 98/22098	05/1998			
	100	WO 98/22619	05/1998			

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Sheet 5 of 17

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	101	US- 5,861,380 A	01/1999	Gyorkos et al.	
	102	US- 5,863,899 A	01/1999	Cheronis et al.	
	103	US- 5,869,455 A	02/1999	Gyorkos et al.	
	104	US- 5,874,424 A	02/1999	Batchelor et al.	
	105	US- 5,874,585 A	02/1999	Gyorkos et al.	
	106	US- 5,891,852 A	04/1999	Gyorkos et al.	
	107	US- 5,914,342 A	06/1999	Maurer et al.	
	108	US- 6,127,356 A	10/2000	Crapo et al.	
	109	US- 6,140,116 A	10/2000	Dinsmore et al.	
	110	US- 6,235,714 B1	05/2001	Paul et al.	
	111	US- 6,323,219 B1	11/2001	Costanzo	
	224	US- 5,281,617 A	01/1994	Kirschenheuter et al	
	225	US- 5,314,910 A	05/1994	Kirschenheuter et al	
	226	US- 5,376,655 A	12/1994	Imaki et al.	
		US-			
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		Country Code ³ "Number" ⁴ "Kind Code" ⁵ (if known)				
	112	WO 98/23565	06/1998			
	113	WO 98/24806	06/1998			
	114	WO 98/46597	10/1998			
	115	WO 98/49190	11/1998			
	116	WO 98/50342	11/1998			
	117	WO 98/50420	11/1998			

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		Country Code ³ Number ⁴ Kind Code ⁵ (if known)	MM-DD-YYYY			
	118	WO 98/56821	12/1998			
	119	WO 97/41231	08/1999			
	120	WO 99/43308	09/1999			
	121	WO 00/52034	09/2000			

Date Considered	
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				Application Number	10/669,250
				Filing Date	September 25, 2003
				First Named Inventor	Leland SHAPIRO
				Art Unit	1645
				Examiner Name	Not Yet Assigned
Sheet	7	of	17	Attorney Docket Number	330310.00103

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	122	Aoki H, Akaike T, Abe K, Kuroda M, Arai S, Okamura R, Negi A, Maeda H. Antiviral effect of oryzacyclatin, a proteinase inhibitor in rice, against herpes simplex virus type I in vitro and in vivo. Antimicrob Agents Chemother Apr. 1995; 39(4):846-9.	
	123	Auerswald et al., "Recombinant leech-derived trypsin inhibitor: construction, production, protein chemical characterization and inhibition of HIV-1 replication", Biol Chem Hoppe Seyler, 375(10):695-703 (1994).	
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	132	Flaitz CM, Hicks MJ. "Molecular piracy: the viral link to carcinogenesis." Oral Oncol Nov. 1998;34(6):448-53.		
	133	Griffin, William C., "Calculation of HLB Values of Non-Ionic Sufactants", [H. L. B.--The Hydrophilic-Lipophilic Balance], J. Soc. Cos. Met. Chem., vol. 5, p. 249 (1954).		
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	141	Lomas DA, Elliott PR, Carrell RW. Commercial plasma alphas-antitrypsin (Prolastin) contains a conformationally inactive, latent component. Eur. Respir J Mar. 1997;10(3):672-5		

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	142	Meylan et al., "HIV infectivity is not augmented by treatment with trypsin, Factor Xa or human mast-cell tryptase", AIDS, 6(1):128-30 (1992).	
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	149	Schwartz, et al., "Antiviral activity of the proteasome on incoming human immunodeficiency virus type I", J Virol, 72(5):3845-50 (1998).	
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	151	Szeghy G, Kenyeres B. On the therapy of herpes simplex keratitis with heparin and trypsin. [Article in German] Klin Monatsbl Augenheilkd 1968; 153(6):827-30.	

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	152	Cilberto et al., 1985, Cell, 41:531-540.	
	153	Dery O. and Bunnett, N.W. Biochem Soc Trans 1999, 27, 246-254.	
	154	Altieri, D.C. J Leukoc Biol 1995, 58, 120-127.	
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	162	Nathan, C. in FASEB J. 1992, 6, 3501.	
	163	Rehman, A. et al. in Br J Pharmacol, 1997, 122, 1702.	
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	172	Schini et al. in Circ Res 1994, 74, 24.	
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				Application Number	10/669,250
				Filing Date	September 25, 2003
				First Named Inventor	Leland SHAPIRO
				Art Unit	1645
				Examiner Name	Not Yet Assigned
Sheet	15	of	17	Attorney Docket Number	330310.00103

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	202	Premack, B.A. et al., "Chemokine Receptors: Gateways to Inflammation and Infection", 1996, Nature Medicine 2:1174-1178.	
	203	Zhirnov O.P. et al., "Antiviral activity of proteinase inhibitors in cultured cells infected with alpha-viruses", Mol Gen Mikrobiol Virusol, 1985, (12):30-6.	
	204	Chesnokova N.B. et al., "Antiproteases in herpetic keratitis", Metab Pediatr Syst Ophthalmol, 1986;9(1):593-6.	
	205	Adelman S.F. et al., "Protease inhibitors suppress fibrinolytic activity of herpesvirus-transformed cells", J Gen Virol, 1982, 60(Pt 1):15-24.	
	206	Chesnokova N.B. et al., "Main proteolytic inhibitors in ocular herpes", Vopr Med Khim, 1981, 27(5):663-5.	
	207	Sharpstone D. et al., "Faecal alpha 1 antitrypsin as a marker of gastrointestinal disease in HIV antibody positive individuals", Gut, 1996, 38(2):206-10.	
	208	Patel et al., "The Role of Protease Drug During Apoptosis", 1996, FASEB J, 10(5):587-597.	
	209	Estaquier J., "Fas-mediated apoptosis of CD4+ and CD8+ T cells from human immunodeficiency virus-infected persons: differential in vitro preventive effect of cytokines and protease antagonists", 1996, Blood, 15;87(12):4959-66.	
	210	Shimizu, T. et al., "DNA Fragmentation induced by Protease Activation in P53-null Human Leukemia HL60 Cells Undergoing Apoptosis Following Treatment with the Topoisomerase I Inhibitor Camptothecin: Cell-Free System Studies", 1996, Exp Cell Res, 1:226(2):292-301.	
	211	Glynn et al., "Apoptosis induced by HIV Infection in H9 T Cells is Blocked by ICE-Family Protease Inhibition but not by a FAS(CD95) Antagonist", 1996, J. Immunol, 1; 157(7):2754-2758.	

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				Filing Date	September 25, 2003
				First Named Inventor	Leland SHAPIRO
				Art Unit	1645
				Examiner Name	Not Yet Assigned
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	212	Ooka, T., et al., "Protective effects of human urinary trypsin inhibitor against trypsin-induced relaxation in rat aorta", Crit care Med, 1996, 24(11): 1903-1907.	
	213	Novradovsky, A., et al., "Endothelial Nitric Oxide Synthase as a Potential Susceptibility Gene in the Pathogenesis of Emphysema in alpha1-Antitrypsin Deficiency", 1999, Am J Respir Cell Mol Biol, 1;20(3):441-447.	
	214	Cordiali Fei et al., "Behavior of several 'progression markers' during the HIV-Ab seroconversion period. Comparison with later stages", 1992, J Biol Regul Homeost Agents, 6(2):57-64.	
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	216	Banfi et al., "Tumor-associated trypsin inhibitor in induced and acquired immunodeficiency. Studies on transplanted and HIV-infected patients", 1991, Scand J Clin Lab Invest 51, Suppl, 207:55-8.	
	217	Deam et al., "Alpha 1-antitrypsin phenotypes in homosexual men", 1989, Pathology, 21(2):91-2.	
	218	Pezzilli et al., "Serum pancreatic enzymes in HIV-seropositive patients", Dig Dis Sci, 1992, 37(2):286-8.	
	219	Tang et al., "Inactivation of HIV-1 by trypsin and its use in demonstrating specific virus infection of cells", 1991, J Virol Methods, 33(1-2):39-46.	
	220	Glozman, "Immunologic functions of enzyme therapy of patients with orchiepidymitis", 1990, Antibiot. Khimioter, 35(7):50-52.	
	221	Franzusoff, et al., "Biochemical and genetic definition of the cellular protease required for HIV-1 gp160 processing", 1995, J Biol Chem, 270(7):3154-9).	

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	222	Gu et al., "Furin is important but not essential for the proteolytic maturation of gp160 of HIV-1", FEBS Lett. 1995, 365(1):95-7.	
	223	Bukrinskaia A.G., "Suppression of rotavirus SA-11 reproduction by protease inhibitors in cell culture", Vopr Virusol, 1987, 32(1):71-4.	

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